SUMMARY OF SAFETY AND PROBABLE BENEFIT

I. General Information

Device Generic Name: Semi-Constrained Prosthesis, finger joint

Device Trade Name: Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis

Applicant's Name and Address: Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Humanitarian Device Exemption (HDE) Number: H010001

Date of Humanitarian Use Device Designation: April 24, 1998

Date of Panel Recommendation: The HDE was not taken to Panel. Refer to Section X of this document for the rationale used in determining that Panel review was unnecessary.

Date of Good Manufacturing Practices (GMP) Inspection: Inspections were performed in June 1997, March 1998, March 2001.

Date of Notice of Approval to the Applicant:

II. Indications for Use

The Avanta MCP Finger Prosthesis is indicated for use in arthroplasty of the MCP joint when either the:

- patient is in need of a revision of failed MCP prosthesis(es); or
- patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic MCP joint.

III. Device Description

The Avanta MCP Finger Prosthesis consists of a distal component which is made of an ultra-high molecular weight polyethylene (UHMWPe) articulating surface and stem, and a proximal component consisting of a cobalt-chromium-molybdenum articulating surface. The joint prosthesis is intended for use with bone cement. The device is semi-constrained because it limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage. The two components of the implant articulate on their mating surfaces.

The proximal component is designed for implantation onto the distal end of the metacarpal. The distal component is designed for implantation into the proximal end of the proximal phalanx. Both components are intended to articulate on each other allowing for 90 degrees of flexion/extension. The articular surfaces prevent dislocation of the joint through simulation of the natural joint implant articular surface. Both the proximal and distal components are designed to be used with cement.

The implant is available in five sizes. An alpha-numeric coding system is used to distinguish sizes. A full surgical instrument set with appropriately sized trials and broaches is available.

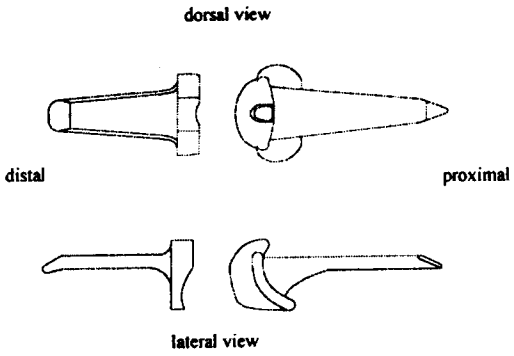

Figure 1. Proximal and distal components of the MCP joint implant in the extended position, lateral and dorsal view.

Materials:

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component
- ASTM F75 cobalt chromium proximal component

IV. Contraindications, Warnings and Precautions

CONTRAINDICATIONS

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation which cannot provide adequate support or fixation for the prosthesis.
- Infection.
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)

- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure when excessive demands are made upon it.

PRECAUTIONS

- **Do not resterilize.** The implant is provided sterile. If either the implant or the package appears damaged, the expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

Patient Counseling Information (See also Warnings)

A patient brochure is available for use in counseling the patient.

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

V. Adverse Effects of the Device on Health

REPORTED ADVERSE EFFECTS

There has been some clinical experience with this device. In the US, 20 patients have been implanted with the Avanta MCP Finger Prostheses with a maximum length of follow-up of 24 months. In the US patients, the most commonly reported adverse events were:

- post operative pain
- subluxation
- dislocation

For more details see **Table 5: Complications for US Patients** in the Clinical Experience Section for reported adverse events associated with the device.

POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks
- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks
- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- instability of the joint
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant

- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

VI. Alternative Practices and Procedures

Conservative early stage treatment includes joint injections, anti-inflammatory drug therapy (e.g., aspirin, Non-steroidal anti-inflammatory drug) and avoidance of heavy stress through the joints (however regular, gentle, active exercises are needed to maintain joint range). Elastic or compressive wrapping of the joints at night may also be used to help control swelling and subsequent morning stiffness. Occasionally, the wrapping may be combined with splinting.

Surgical intervention may restore some range of motion and is typically used when conservative measures no longer give relief. Surgical treatment may include fusion of the bones together, interpositional arthroplasty with a tendon, or joint replacement surgery with a silicone spacer implant. Individuals who are very active and use their hands heavily may not be good candidates for silicone implants.

VII. Marketing History

Since 1996 to the present, the device has been exported to many countries including Australia, Canada, France, Italy, Japan, Netherlands, Portugal, Spain, Switzerland. The device has received the CE Mark for marketing in Europe.

The Avanta MCP Finger Prosthesis has not been withdrawn from the market for any reason related to safety or probable benefit of the device.

VIII. Summary of Studies

Both pre-clinical (biocompatibility and mechanical) and clinical testing were performed using the device.

A. Pre-clinical Testing

The device is constructed from materials commonly used in other total joint replacement devices. Therefore, extensive biocompatibility testing was not necessary to establish the safety of the materials used in the construction of this device. Table 1 contains a summary of the biocompatibility testing performed on the device.

Table 1. Biocompatibility testing performed.

Test Protocol	Results
Minimal Essential Media (MEM) Elution	Pass
Limulus Amebocyte Lysate (LAL) Test	Pass
Bioburden Counts	<1 colony forming unit

Additional pre-clinical testing of the device design included fatigue testing, wear testing, and cadaver evaluations. The cadaver evaluations were used to evaluate ease of implantation using the recommended surgical technique.

Fatigue analysis of the MCP joint was conducted. The UHMWPE component was mounted at a flexion angle of 30 deg. Testing was performed on an Instron 1321 bi-axial servohydraulic universal testing machine using a load control sinusoidal input wave, 4 to 44 lbs, operating at a frequency of 10 HZ. Data

was collected at 1,000 cycle intervals up to 10,000 cycles after which collection was performed at 10,000 cycle intervals until the completion of the 10,000,000 cycle test. All testing was performed in adult bovine serum (100%). No mechanical failure of the five MCP specimens occurred during the 10,000,000 cycle duration test.

Wear analysis of the MCP joint was conducted using a device designed to model the flexion/extension of the MCP joints of the hand. Implants were mounted in synthetic bone bonded to a cylindrical stainless steel sleeve. Implants were submerged in adult bovine serum (100%). Initially, the implants were aligned in a position equivalent to 45 degrees of flexion. The spring force was adjusted to transmit a downward force of 26.4 lbs., while maintaining the out of plane forces at zero. Testing was performed at a rate of 2.5 Hz to a total of 10,000,000 cycles.

The results of the mechanical testing (fatigue and wear) indicate the device should have adequate mechanical properties for use in MCP arthroplasty when the patient is in need of a revision of failed MCP prosthesis(es); and the patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic MCP joint.

Table 2 summarizes the mechanical test results.

Table 2. Mechanical testing.

Test Protocol	Samples	Results
Fatigue	5 implants	No failures reported
Wear	5 implants	Average wear rate: 3.12 $mm^3/10^6$ cycles

B. Clinical Experience:

There has been some clinical experience with this device. In the US, 20 patients have been implanted with the Avanta MCP Finger Prostheses with a maximum length of follow-up of 24 months in a prospective randomized clinical study. Patients are randomized into either the experimental group, which received the Avanta MCP Finger Prosthesis, or into the control group, which received a silicone elastomer implant. Thirty-four patients have been randomized into the study to date. However only 29 of these patients, 20 experimental and 9 control, have had surgery performed to implant either the control device or the Avanta MCP Finger Prosthesis. Table 3 describes the patients randomized into the study, patients implanted with a device and the patient dropouts from the study. Twenty nine of these patients have follow-up data, which is summarized in Tables 4-6. Tables 4-6 describe the patient demographics, reported complications and length of follow-up for this clinical study to date.

Table 3. US Patients MCP

Patient Category	*Patients with Avanta MCP implant (patients)*	*Patients with Silicone Implant (patients/hands)*	*Total (patients/hands)*
Total Randomized into Study	20	14/15	34/35
Total Who Have Had Surgery	20	9/10	29/30
Withdrew Prior to Surgery	0	5	5
Withdrew After Surgery	5	2	7
With follow-up Data*	20	9/10	29/30

* Data report forms have been returned on 29 patients. Tables 4-6 describe the clinical results for these 29 patients.

Table 4. Demographics for 29 US Patients* with Follow-up

Category	*Patients with Avanta MCP Implant*	*Patients with Silicone Implant*	*Total*
Male	3	1	4
Female	16	8	24
Unknown	0	1	1
Mean Age, SD	56.3±11.3 (n=19)	61.9±8.1(n=6)	58.2 ±10.3
Age Range (years)	32-77	52-74	32-77
Osteo-arthritis	1	1	2
Polymytosis	0	1	1
Rheumatoid Arthritis	18	7	25
Silicone Implant Revision	1	0	1

*Description of number of patients with more than one implant. There are 29 patients with 99 implants: twenty patients with 4 implants; three patients with 3 implants; three patients with 2 implants; four patients with 1 implant.

Table 5. Complications for US Patients

Complication	*Avanta MCP Device (n=8 Patients)*	*Silicone Device (n=0 Patients)*
Skin Necrosis	1	0
Wound Dehiscence	1	0
Implant Failure	1	0
Joint Dislocation	3	0
Joint Subluxation	4	0
pain (6 months post-op)	4	0

Table 6. Number of US Patients (Implants) at Each follow-up Time Point

Length of follow-up	*Avanta MCP Implant Patients (# implants)*	*Silicone Implant Patients (# implants)*
Post-op (1-4 weeks)	20 (68)	9 (31)
3 months	18 (61)	8 (29)
6 months	16 (53)	6 (21)
12 months	9 (32)	2 (12)
24 months	4 (14)	2 (5)
Post-op withdrawal	5(20)	2 (5)

Linscheid[1] reported on sixty-one fingers in 25 patients treated with this device. Eight implants were implanted in eight patients with traumatic or degenerative arthritis. Fifty-three implants were implanted in 17 patients with rheumatoid arthritis. There were 23 women and 2 men, with an average age of 63 years (range = 45-78 years). The average preoperative MCP arc of motion was 45 degrees, with an extension lag averaging 45 degrees. Preoperatively, there was an average of 20 degrees of ulnar deviation. Swan-neck deformities were common in those patients with rheumatoid arthritis.

The follow-up averaged 30 months (range = 4-60 months). The results in single joints with traumatic or degenerative arthritis were better than in the multiple fingers with rheumatoid arthritis. The average arc of motion was 50 degrees (range 25-90 degrees). Extension lag was improved in the rheumatoid patients. The author stated, "Grip and pinch strength showed little change, but discomfort was noticeably better subjectively." The author only reported "Subluxation or dislocation recurred despite repair of the collateral ligaments and recentering of the extensor tendon." The report did not provide the rate of these adverse events. The author states that this complication was addressed through postoperative splinting, or casting, and careful monitoring of joint reduction through the use of x-ray.

IX. Conclusions Drawn from Studies

The pre-clinical testing indicates the device design is adequate for its intended use. More specifically, the performance testing to assess mechanical properties demonstrates the fatigue and wear properties of the device are acceptable; the biocompatibility testing indicates the device is non cytotoxic, pyrogen free and can be sterilized; and the cadaveric testing shows the device can be implanted using the suggested surgical technique.

The limited clinical data available indicates no unexpected risk of illness or injury from use of the device compared to other surgical treatment options.

In a comparison to alternatives such as the silicone elastomeric constrained MCP implant, the Avanta Orthopedics MCP joint implant has the following features: 1) semi-constrained design leads to a greater range of motion; 2) metallic and polymeric design eliminates the potential for silicone synovitis; and 3) metallic and polymeric semi-constrained design may reduce the frequency of implant fractures associated with the silicone constrained implant.

The Avanta Orthopedics MCP joint implant pre-clinical and clinical data suggest that the device will not expose patients to an unreasonable or significant risk of illness or injury, and that the probable benefit to health from use of the device outweighs the risk of injury or illness.

X. Panel Recommendation

This HDE was not taken to a meeting of the Orthopedics and Rehabilitation Devices Panel because other finger prostheses marketing applications have previously been reviewed by this panel. Therefore, it was determined the Panel had already provided input into acceptable kinds of pre-clinical testing needed for a marketing application.

XI. CDRH Decision

CDRH determined that, based on the data submitted in the HDE, the Avanta Orthopaedics MCP joint implant will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risks of illness or injury, and issued an approval order on _____.

XII. Approval Specifications

Instructions for Use: See Labeling (Attachment 1)

Indications for Use: See section II above.

Hazards to Health from Use of the device: See Sections IV and V above.

XIII. Publications and Other Outside Information

1. Linscheid R.L., **Metacarpophalangeal arthroplasties: prosthetic design considerations.** *Hand Arthroplasties Federation of European Societies for Surgery of the Hand, June 2000.*